

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

FOR

Self-Retaining Retractor

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Self-Retaining Retractor**Cross Reference to Related Applications**

The present application claims priority from U.S. Provisional Application, Serial No. 5 60/395,234, filed July 11, 2002, which is incorporated herein by reference.

Technical Field and Background Art

The invention relates to surgical devices and methods, and in particular to devices and methods for vaginal and perineal surgery.

In present techniques for vaginal surgery, it is necessary for a surgeon to be assisted by other personnel during an operation in order to retract the vaginal walls. Typically, a weight retractor is used to retract the back wall of the vagina while the assisting personnel retract the other walls of the vagina. The presence of the other personnel to assist in retraction can make the surgery more difficult by crowding the surgeon's range of motion. It may also be more costly for the surgeon, and prevent the personnel who are assisting in retraction from performing other tasks to aid in the surgery.

Summary of the Invention

In an embodiment of the invention, a retraction device for gynecological procedures on a patient comprises a frame attached to a handle and at least one retractor adjustably mounted to the frame. The frame may have one or more fissures that hold suture material during a surgical procedure. The frame may be attached to the handle with a hinge. In a particular embodiment, the hinge includes a ratchet mechanism.

In another embodiment of the invention, the retraction device includes a jig for adjustably mounting the retractor to the frame. The frame of the retraction device may include a track or rail; the retractor may be mounted to the track or rail with the jig. 25 Alternatively, the frame may include a slot, which may be corrugated, in which the jig is positioned in the slot. Another alternative includes having a portion of the edges of the

frame corrugated, the jig configured to contact the edge of the frame. The jigs used in embodiments of the invention may include locks.

In an alternate embodiment of the invention, a retraction device includes a support element that is attached to the handle for retaining the device in a position. The support 5 element may include a sheet capable of retaining the device using the weight of the patient. Alternatively, the support element may include a sheet attached to at least one rod, the rod being configured to fit into a track. A support element may also comprise a bar which is attachable to a table. A bracket or a jig may be used to attach the support element to the handle of the retraction device.

10 In other embodiments of the invention, a retraction device includes one or more of the retractors having a curved blade, and a retractor-handle attached to the frame. The retractor-handle may have a groove along a portion of the length of the retractor-handle; the groove having differential width in varying portions of the groove. The retractor handle may be attached to the frame with a jig. A hinge may be used to attach the curved blade to the 15 retractor-handle. The hinge may include a ratchet-type mechanism or be configured as a ball-type hinge. The curved blade of a retractor may be configured to form a groove capable of supporting another blade. The retraction device may include an anterior retractor, a posterior retractor, or a side retractor.

According to another embodiment of the invention, a method of retracting the walls 20 of a patient comprises: providing a retraction device including a frame, and a plurality of retractors mounted on the frame; and retracting the vaginal walls with the retractors, such that the frame maintains a separation of the retractors and the vaginal walls. The method may provide for a retraction device that includes a handle for mounting the frame in a desired position. The method may also provide for a retraction device with means of 25 adjustably mounting the retractors on the frame.

Brief Description of the Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1 shows a handle and frame of a self-retaining retractor device according to an embodiment of the invention;

Fig. 2 shows a cross-sectional view of the frame of the self-retaining retractor of the embodiment of Fig. 1;

5 Fig. 3 shows a frame with a groove through which a jig runs to support a retractor according to an embodiment of the invention;

Fig. 3A shows a cross-sectional view of the self-retaining retractor device of the embodiment of Fig. 3;

10 Fig. 4 shows a frame with a corrugated groove through which a jig runs to support a retractor according to an embodiment of the invention;

Figs. 4A and 4B show a jig which may be used with the frame of Fig. 4;

Fig. 5 shows a frame with a corrugated edge to which a jig may attach, supporting a retractor, according to an embodiment of the invention;

Figs. 5A – 5C show a jig which may be used with the frame of Fig. 5;

15 Fig. 6 shows a self-retaining retractor device with a support element to support the device using the weight of a patient according to an embodiment of the invention;

Fig. 7 shows a self-retaining retractor device with an anterior retractor having a blade supported by a curved blade and a table-mounted support element according to an embodiment of the invention;

20 Fig. 8 shows a side view of an anterior retractor for a self-retaining retractor device according to an embodiment of the invention;

Fig. 9 shows a perspective view of an anterior retractor for a self-retaining retractor according to an embodiment of the invention;

25 Fig. 10 shows a side view of a retractor for a self-retaining retractor device in which the blade and retractor-handle are attached with a ball-hinge according to an embodiment of the invention;

Fig. 11 shows a long blade for use with an anterior retractor according to an embodiment of the invention;

30 Fig. 12 shows a top view of a posterior retractor for a self-retaining retractor device according to an embodiment of the invention;

Fig. 13 shows a view of a side retractor for a self-retaining retractor device according to an embodiment of the invention;

Fig. 14 shows a side view of either a side or posterior retractor for a self-retaining retractor device according to an embodiment of the invention;

5 Fig. 15 shows a retractor without a slot for a self-retaining retractor device according to an embodiment of the invention;

Fig. 16 shows a jig that may be used with the retractor depicted in Fig. 15;

Fig. 17 shows a support element for a self-retaining retractor according to an embodiment of the invention;

10 Fig. 18 shows side view of a table-mounted support element configured to fit into a cylindrical track of a table for a self-retaining retractor according to an embodiment of the invention;

Fig. 18A shows a perspective view of the support element of Fig. 18;

15 Fig. 19 shows another support element for a self-retaining retractor utilizing a bar as wide as an operating table according to an embodiment of the invention;

Fig. 20 shows a bracket to attach a support element to the handle of a self-retaining retractor device according to an embodiment of the invention;

Figs. 21A and 21B show bottom and top views of a jig for a self-retaining retractor according to an embodiment of the invention; and

20 Figs. 22A and 22B show bottom and top views of an alternative embodiment of a jig.

Detailed Description of Specific Embodiments

Fig. 1 shows a handle and frame of a self-retaining retractor device, according to an embodiment of the invention, that removes the need for personnel to assist a surgeon in keeping the vaginal walls or perineal incision retracted, and allows for smooth, complete retraction of the side walls, with the best possible surgical field; the device may be set up by a surgeon without assistance. A racket-shaped rigid frame 1 contains a track 2 along which a surgeon may smoothly adjust the location of a set of retractors, without the need for assisting personnel. A handle 4 is connected to the frame 1 by a hinge 3, so that the frame 1 may be moved to firmly contact the patient. A ratchet mechanism 6 near the hinge allows the angle

between the frame **1** and handle **4** to be adjusted, while holding the frame **1** in place against the patient. In one embodiment according to the invention, the major axis of the frame is, for example, 14 cm. in length, while the minor axis is 12 cm. in length.

Fig. 2 shows a cross-sectional view of the frame of the self-retaining retractor device 5 of the embodiment of Fig. 1. A raised portion **101** of the frame's cross-section functions as a rail, along which the surgeon may slide a set of jigs (depicted in Fig. 21) that are attached to the retractors (also discussed below). The reverse side **102** of the frame contacts the patient, and is smooth, so that the jigs for the retractor may be moved around the raised portion **101** on the reverse side of the frame without directly touching the patient.

10 The embodiment of Fig. 1 depicts one mechanism for mounting one or more retractors to the frame of the device. However, embodiments of the invention include any means by which a retractor may be adjustably mounted to the frame of the device, and are not limited to the use of a track or rail or jig. Several non-limiting examples are discussed herein.

15 Fig. 3 shows the track **2** could be substituted by a groove **35** that runs along the length of the frame. Through the groove runs a jig **36** (shown in Fig. 3A) comprised of a screw with a flat circular lower end **37** and a spring-loaded sheet of metal **38** to support its place on the groove, the upper end will be a screw and a flange-nut combination **39** to hold the different retractors.

20 Fig. 4 shows the track **2** could be substituted by a corrugated groove **40** that runs along the frame. Through the groove a jig **41** (shown in Figs. 4A and 4B) comprised of a body with a cavity **42**. A pin **43** at its open end holds two arms **44** in a scissors manner to engage to the dents in the grooved track **40**. These arms are kept in the open position by the help of spring metals **45**. A screw and flange-nut combination attached to the body may be 25 used to hold the different retractors.

Fig. 5 shows the frame with smooth front and back surfaces, and outer and inner edges which are corrugated **46** and along which a jig may be run. The jig (shown in Figs. 5A – 5C) is comprised of a body **47** with a cavity **48** in which two parallel arms **49** held by two deferent pins **50**. The two arms are kept in the retracted position by the help of metal spring 30 **51**. A screw and flange-nut combination attached to the body to hold the deferent retractors.

Persons skilled in the art will readily realize that the frame of the retraction device may take on a variety of shapes that are convenient for holding retractors during gynecological procedures; the frame is not limited to the shape shown in Fig. 1. As an example, an embodiment of the invention may include a frame, as shown in Fig. 5, that alters 5 the frame shape to include a lower portion curved **55** into the space enclosed by the frame in order to allow retractors to be attached closer to one another.

Returning to Fig. 1, a groove **5** in the handle **4** of the retraction device allows a support element (discussed further below) to attach to the handle **4**; circularly widened portions of the groove **5** allow room for a screw and flange-nut combination (shown 10 elsewhere) to attach the support element to the handle **4**. The vertical position of the retraction device during surgery may be adjusted by moving the position of the screw and flange-nut combination to different positions in the groove **5**. As shown further below, a screw and flange-nut combination **7** holds the posterior retractor to the frame, while screw and flange-nut combination **9** holds the anterior retractor to the frame. As is apparent to 15 those skilled in the art, the adjustment of the support element relative to the handle may be carried out by a variety of mechanisms, not limited to the specific embodiment described here.

Small fissures **8** in the raised portion **101** of the frame, shown in Fig. 2, may be used to allow holding of suture material for tagging or retraction, during surgery. Such fissures 20 may, for example, contain projections that hold the suture material in position once the suture is pulled through the fissure in one direction, and from which the suture may be released when desired.

Fig. 6 shows an assembled view of a self-retaining retractor device, according to an embodiment of the invention. In the embodiment shown in Fig. 6, four movable retractors 25 **10**, **17**, **21** (one on each side) are used, including an anterior retractor **10**, a posterior retractor **17**, and two side wall retractors **21**; typically, from two to four retractors may be used, but other numbers may also be used in accordance with embodiments of the invention. Three alternative versions **25**, **31**, and **34** of a support element are shown in Figs. 6, 7, 17, 18, and 19. The first version **25** of the support element allows the device to be retained in position 30 for surgery by the patient's weight, by having support element **25** held between the patient's buttocks and the operating table. The second and third versions **31** and **34** (described later)

of a support element allow the handle 4 to be attached to the operating table using the support element.

Fig. 7 shows an oblique view of fully assembled self-retaining retractor device when utilized on patient. The view shows the retractors 10, 17, 21 fully extended and the angle of 5 the anterior retractor open to its greatest extent. Further reference numerals indicated in Fig. 6 and 7 are discussed in each of the detailed component views of the remaining figures.

Figs. 8 and 9 show a side view and a perspective view, respectively, of an anterior retractor 10 for a self-retaining retractor device according to an embodiment of the invention. A paddle or blade 11 of the anterior retractor has curved sides (see Fig. 3B) that allow a 10 longer blade to be slid into the curved blade 11 as necessary during surgery. Blades of varying lengths may be utilized with the curved blade as desired. The blade 11 is attached to the anterior retractor's handle 12 by a hinge 14, which allows gentle widening of the angle of retraction according to the desire of the surgeon. A ratchet mechanism 15 allows the angle of the blade 11 with respect to the handle 12 to be adjusted, while holding the blade 11 at the 15 chosen angle. Similar hinge and ratchet mechanisms may be used on other retractors (such as a posterior retractor or side retractor) in accordance with embodiments of the invention. Other mechanisms may also be used to hold a particular angle of the blade with respect to the handle. As another example, shown in Fig. 10, a screw and nut combination 56 may be used to attach a retractor blade to the frame with a ball type hinge 57 that allows adjustment of the 20 angle of the retractor blade.

In a particular embodiment, a groove 13 in the handle 12 allows attachment of the anterior retractor 10 to the frame 1 using a jig (as shown in Figs. 6 and 7), and contains an area of circular widening to allow room for a flange-nut of the jig (shown further below). The vertical position of the anterior retractor 10 may also be adjusted by moving the position 25 of the flange-nut in the groove 13.

Fig. 11 shows a long blade 16 for use with an anterior retractor, in accordance with an embodiment of the invention. The long blade 16 may be inserted into the groove of the anterior retractor's blade 11 in order to give a deeper view of the surgical field. Similar blades of varying lengths may be fitted into other retractors (such as the posterior retractor 17 30 or side retractors 21) in accordance with embodiments of the invention.

Fig. 12 shows a top view of a posterior retractor 17 for a self-retaining retractor device according to an embodiment of the invention. The posterior retractor 17 has a curved paddle or blade 18 and a handle 19. As with the anterior retractor, a groove 20 in the handle 19 has areas of circular widening to allow room for a flange-nut of a jig (shown further below) that attaches the posterior retractor 17 to frame 1 (as shown in Figs. 6 and 7). Groove 20 also allows for adjustment of the vertical position of posterior retractor 17. Fig. 13 shows a view of a side retractor 21 in accordance with an embodiment of the invention, which similarly features a curved paddle or blade 22, a handle 23, and a groove 24 in the handle for attachment of the retractor (as shown in Fig. 7). Groove 24 allows for adjustment of the lateral position of the side retractor 21. Fig. 14 shows a side view corresponding to either a posterior or side retractor, according to embodiments of the invention.

The grooves 13, 20, 24 in the retractors 10, 17, 21 exemplify one embodiment of the invention that enables the retractors to be attached to the frame. As is apparent to those skilled in the art, other retractor designs may be used to attach the retractors to the frame in accord with embodiments of the invention. Another example, shown in Figs. 15 and 16, depicts the retractor-handles being made of solid metal 52. Each retractor is held in place by a jig made of two sheets of metal 53. The lower sheet will have a notch 54 for attaching to the retractor. The jig described above may be used to replace any of the jigs utilized herein (e.g. jigs used with the retractor-handle, the frame handle, or support structure); a slot or groove need not be utilized when this type of jig is substituted.

Fig. 17 shows a support element 25 for a self-retaining retractor device according to an embodiment of the invention, which allows the device to be retained in position for surgery by the patient's weight, by having support element 25 held between the patient's buttocks and the operating table. Support element 25 attaches to the handle 4 (see Fig. 6). Support element 25 may be made, for example, of a stainless steel sheet, with a right angle bend 26 at its outer end. A jig, which may use a screw and flange nut combination in a similar fashion to the jigs described below in Fig. 21, allows attachment of the support element 25 to the handle 4, as shown in Fig. 17. A bracket 28 may replace the jig, as shown in Fig. 20. The bracket 28 may be made of a stainless steel metal sheet that is folded over approximately one-third of its length. The bracket 28 may be placed over the right angle bend 26. The bracket 28 may be attached to the support element 25 by screws. The bracket

28 will have a screw **29**, to attach the bracket **28** to the support element **25**, and flange-nut combination **27** on its front to which the handle **4** may be attached, as shown in Figs. 6 and 20. Sterile drapes may be used to cover the right angle bend to prevent patient contact with the jig, bracket **28** or handle **4**.

5 Figs. 7, 18, and 18A show an alternative table-mounted support element **31** for a self-retaining retractor device according to an embodiment of the invention. Support element **31** includes two cylindrical rods **32** (with spring type sheet on one side), attached to a sheet of metal **33**. The rods **32** are configured to fit into a cylindrical track that most operating tables possess. Bracket **28** may be placed over the metal sheet after being covered by sterile drapes
10 to secure the support element **31** to a handle **4**, as described above. Alternatively, a jig may be used instead of a bracket **28**, also described earlier.

15 Fig. 19 shows another table-mounted support element **34** for a self-retaining retractor device according to an embodiment of the invention. Support element **34** includes a bar that is as wide as the operating table, and contains notches in its side members to hook to the operating table. Bracket **28** may be placed over the support element **34** after being covered by sterile drapes to secure the support element **31** to a handle **4**, as described above.
Alternatively, a jig may be used instead of a bracket **28**, also described earlier.

20 Figs. 21A and 21B show bottom and top views of a jig **60** for a self-retaining retractor device according to an embodiment of the invention. Jig **60** may be used, for example, to movably attach retractors **10**, **17**, and **21** to the frame **1** (as shown in Figs. 6 and 7), so that the retractors may be smoothly moved around frame **1** to achieve the best retraction for the surgical field. A body **61** of jig **60** contains a groove **62** that fits around the raised portion **101** (see Fig. 2) of the frame's cross-section, so that the jig **60** may slide around the frame **1**. A lock **63**, which may use an out-of-center wheel **64**, may be used to
25 lock the jig **60** in position on the frame **1**. The lock may be used by turning the lock's handle to tighten the jig's grip on the track once the desired location for the retractor on the frame is reached. A screw **65** extends from the body **61** of the jig **60**. After placing the handle groove of a retractor (such as retractor **10**, **17**, or **21**), or groove in another component to be attached, over the screw **65**, a flange-nut **66** secures the component to the jig **60**. As shown
30 in Figs. 22A and 22B, the out-of-center wheel **64** may be replaced by two curved spring metals **67**, which are attached to the lower part of the jig **60** that is in contact with the frame

body 1; the spring metals 67 keeping the jig 60 in tight contact with the track, and holding the jig 60 in a desired position.

The following description provides a non-limiting example of how the self-retaining retractor device may be used. The desired support element 25, 31, 34 is placed under the patient or attached to the operating table. Sterile drapes are used to cover the patient and support element. The handle 4 is firmly attached to the supporting element 25, 31, 34 using either a jig or bracket 28, which is placed on top of the supporting element 25, 31, 34, and a screw and flange-nut combination. The position of the handle 4 is chosen to obtain the correct vertical height for the frame 1. The blade of the posterior retractor 17 may be inserted into the patient first, and then secured to the frame 1 by a screw and flange-nut combination. Then the blade of the anterior retractor 10 may be inserted, and secured to the frame; its vertical position and position on track 2 may be adjusted; and its angle may be adjusted using ratchet mechanism 15. Then the side retractors 21 may be inserted, and their lateral position and position on track 2 adjusted. However, the particular order of insertion of the retractors, as well as their positioning and angling, may be adjusted according to the nature and progress of the surgery, as will be recognized by those of skill in the art in accordance with the disclosure herein.

Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.